‘No-Blame’ Redress Scheme in Scotland for Harm Resulting from Clinical Treatment

RESPONDENT INFORMATION FORM

Please Note this form must be returned with your response.

Are you responding as an individual or an organisation?

☐ Individual
☒ Organisation

Full name or organisation’s name

Healthcare Improvement Scotland

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☒ Yes
☐ No
“No-blame” Redress Scheme in Scotland for Harm Resulting from Clinical Treatment

Questions:

1. The Ministerial commitment is that any scheme will contribute to patient safety, learning and improvement and we would therefore propose to integrate the scheme with the NHS Scotland feedback, complaints, adverse incident reporting and Duty of Candour processes as the scheme is being developed.

2. Under the national approach to learning from adverse events set out in the National Framework issued by Healthcare Improvement Scotland (HIS)\(^1\) and the forthcoming introduction of a statutory duty of candour\(^2\) in health and social care settings, the patient (and their families) should be informed when and why an error, which has resulted in harm, has occurred. A report setting out details of the incident and the report of the full investigation will be prepared and will be used in consideration of whether the eligibility criteria for redress has been met.

**Question 1:** Do you agree that it is appropriate to integrate the process for the redress scheme with the incident investigation, duty of candour and complaints processes to ensure consistency, improvement and shared learning?

Yes ☒ No □

We agree it will be important to integrate these processes, and look forward to contributing further to any consideration as to what this would mean in practice, both from the perspective of patients and their carers/families, and for service providers.

If you disagree please briefly explain why:

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\(^2\) [http://www.scottish.parliament.uk/parliamentarybusiness/Bills/89934.aspx](http://www.scottish.parliament.uk/parliamentarybusiness/Bills/89934.aspx)
3. Eligibility criteria are a feature of all ‘no fault’ or ‘no-blame’ schemes worldwide, with common features including: thresholds, limitations on the extent of cover and additionally limitations or caps are applied to the sums payable. In working to scope and shape a fairer and importantly affordable Scottish scheme a number of approaches were considered. Those options have been narrowed down and our preferred approach for the initial establishment and testing of a no-blame redress scheme in Scotland is set out in this paper.

4. Additional information gathered for the NHS in Scotland in relation to complaints, adverse events and claims has been considered. This has permitted further exploration of possible approaches for the development of eligibility criteria which would allow the introduction of a fairer, faster and simpler approach to handling compensation claims and one which is affordable. The proposal is that the scheme will be based on the following broad principles:

- Compensate quickly and fairly for avoidable harm where the investigation establishes the harm would have been avoided by the use of ‘reasonable care’. (Will exclude cases where the unfavourable outcome was one of the unavoidable risks of the procedure.)
- Defend medically reasonable care
- Reduce patient injuries (and therefore claims) by learning from patients’ experiences

**Question 2 - Do you agree with the broad principles for the scheme?**

Yes ☒ No ☐

These principles seem reasonable but it will be important to ensure they are understood by all, and the potential challenges in implementing these principles. A local significant adverse event review can take some time to conclude, especially in the most complex cases. The national guidance timescale is 3 months to complete a significant adverse event review, but often these can take longer due to capacity and capability within NHS boards to perform reviews. There will also need to be some independent quality assurance process of local reviews for the purposes of this scheme, and it needs to be acknowledged that avoidability will not always be easy to determine – it will often not be a binary issue but something that will have a degree of subjectivity. This should be improved with the introduction of an agreed process to determine avoidability.

We agree that learning from experience to help minimise future harm should be an aim of this scheme but it needs to be emphasised that healthcare is high risk, and although we can seek to minimise these risks by learning from past experiences, we will never eliminate risk.

We would like to see the inclusion of a principle relating to ensuring accessibility of the scheme. The consultation paper does not address the important issue of how patients and their carers/families will be informed about the scheme, or what advice and support will be available to them, for example, through the Patient Advice and Support Service, or whether legal aid may be available to obtain legal support.
5. Given the concerns highlighted at 2.3 of the consultation document (in relation to the original Recommendation 2) we would propose that, as in Sweden, the eligibility criteria should be structured around the notion of ‘avoidability’; i.e. the test is whether the harm caused by the treatment was avoidable. The proposed scheme will therefore be ‘no-blame’ rather than a true ‘no-fault’ scheme, which would potentially cover avoidable and unavoidable harm. The Swedish scheme also uses the ‘experienced specialist rule’, under which consideration is given to the risks and benefits of treatment options other than the one adopted and a retrospective approach has been taken in some cases in the evaluation of whether the injury was avoidable.

6. The draft proposals for the no-blame redress scheme combine a new approach for dealing with compensation for causally connected avoidable harm where the harm has been or is likely to be, experienced by the person for a continuous period of at least 6 months with improvements to the existing legal process.

Question 3 - Do you agree that eligibility should be structured around the notion of ‘avoidability’?

Yes ☒ No ☐

We agree that eligibility should be structured around avoidability. However, it may be challenging to agree whether the harm was avoidable or not. There are a number of tools and outcome codes that are already being used by NHS boards to determine if an adverse event was avoidable or not following a review. These are detailed in the national framework for learning from adverse events and copied below:

1. Appropriate care - The adverse event review concluded that the care and/or service was well planned and appropriately delivered; no care or service delivery problems were identified; and the adverse event outcome was ultimately unavoidable. However, it is likely there are still learning points (especially good practice points).

2. Indirect system of care issues - The adverse event review identified indirect or incidental sub-optimal care or service issues and lessons that could be learned (and good practice points), however, these were unlikely to have affected the final outcome. For example, a protocol was not strictly followed or there was a delay in accessing the patient notes, but these were unlikely to have affected the final outcome.

3. Minor system of care issues - The adverse event review identified minor or sub-optimal care or service provision and that a different plan or delivery of care/service may have resulted in a different outcome. For example, system or management factors were identified (such as incomplete records or a delay in transferring the patient or service user), but there was uncertainty regarding their impact on the final outcome. Learning
points have been identified and improvement plans developed.

4. **Major system of care issues** - The adverse event review identified that a different plan and/or delivery of care or service would, on the balance of probability, have been expected to result in a more favourable outcome. Factors were identified which negatively influenced or contributed to the adverse event outcome. For example, how the case was managed had a significant impact on the level of harm. Learning points have been identified and improvement plans developed.

Based on these outcome codes, would it be only events that were reviewed as having major system of care issues (4) that would be compensated or would events where minor system of care issues (3) were identified that could have potentially led to the adverse outcome also be compensated?

There is also the need to consider that ‘avoidable harm’ will change as clinical care and treatment continues to develop. For example, it was previously considered that acquiring an infection while in hospital was an unavoidable event but now we know this is avoidable with the right infection control processes in place.

If you disagree please briefly explain why:

**Question 4** - Do you support the proposal that the non-retrospective scheme should be restricted to harm which has been or is likely to be, experienced by the person for a continuous period of at least 6 months?

Yes ☑️ No ☐

Some criteria is required and this seems sensible and in line with the duty of candour provisions.

If no, please briefly explain why:

7. In the first instance it is proposed that the Redress Scheme would be restricted to payment of compensation where the harm has been or is likely to be, experienced by the person for a continuous period of at least 6 months and is as a result of clinical treatment administered by directly employed NHS staff in
Scotland. The scheme will not be retrospective (i.e. will cover clinical events that occur after the date of introduction). It will, take account of health and social care integration and therefore clinical treatment provided as part of an integrated service.

8. The No-fault Review Group also recommended that the scheme should cover all medical treatment injuries that occur in Scotland and should extend to all registered healthcare professionals in Scotland, and not simply to those employed by NHSScotland. However, in response to the earlier consultation a good deal of concern was expressed about the cost and complexity of introducing a scheme which extended beyond the NHS. Therefore, it is proposed that in the first instance the scheme be limited to clinical treatment provided by directly employed NHS staff in Scotland (independent contractors – GPs, dentists, opticians and pharmacists – would be excluded along with private providers) with options to extend, if considered appropriate, at a later date.

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<th>Question 5 - Do you support the proposal that the proposed non-retrospective scheme should in the first instance be restricted to clinical treatment provided by directly employed NHS Staff in Scotland?</th>
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<td><strong>Yes</strong> ☐ <strong>No</strong> ☒</td>
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If no, please briefly explain why:

The scheme needs to be fair, equitable and easy to understand. For most people they do not understand that the majority of primary care services are contracted by the NHS board. A member of the public should have access to the same level of redress if the harm occurs in primary care or secondary care. Also there is the potential for inequity in the scheme as there are pockets of salaried GPs across Scotland that would be covered by this scheme while the majority of care provided by GPs would not be. This scheme could be restricted to NHS care, but should be inclusive of all NHS care. It will also need to take account of health and social care integration, and potentially need to expand to cover social care.

Additionally, if we truly want to develop an open, learning culture then we need to move away from a liability based approach where NHS boards protect their liability and contractors to the NHS board protect theirs. NHS boards are responsible and accountable for all healthcare provided to their resident population, including that care they contract out to third parties. If this restriction is due to affordability then consideration should be given to existing mechanisms for apportioning liability between separate organisations.

It is unclear whether the reference to ‘clinical treatment’ in the question means that ‘failure to treat’ and ‘faulty equipment’ (as referred to in recommendation 3 of the No-fault Review Group) would also be covered. We believe that these should either be covered by the scheme, or that a clear rationale should be offered for their exclusion, including setting out what this will mean in practice for patients and their carers/families.

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3 A “clinical” event can be broadly considered to be an incident arising directly from treatment.

9. Currently around 70% of all awards made under the current CNORIS system are under £100,000. We are proposing that the No-blame redress scheme will handle claims up to £100,000.

10. The cap of £100,000 on the level of award payable under the scheme (including cost of care packages and damage for loss of earnings) will effectively exclude the most severe and complex cases (e.g. brain damaged children) and those cases where continuing care is appropriate. These cases would continue to be handled through the legal system. (Please also see proposals in relation to continuing care costs explained at Item 6 in the Consultation paper.)

11. The Breach of Duty of Care principles would continue to be applied to claims being handled through the legal system. However, these claims will benefit from the introduction and compulsory use of a Pre-action Protocol currently being developed by The Personal Injury Committee of the Scottish Justice Council. The protocol will be used within the existing Clinical Negligence and Other Risks Indemnity Scheme (CNORIS) and will allow for speedier and more transparent outcomes in clinical negligence legal claims.

**Question 6 - Do you support a cap of £100,000 on the level of award under the proposed scheme?**

Yes ☒ No ☐

There needs to be some cap to make this scheme affordable, and based on the current awards this seems reasonable and would improve the current system for the majority of claimants. However, it would be helpful if a fuller rationale was provided as to why around 30% of cases will be excluded, given what this will mean in practice for those individuals, who will not benefit from the scheme. How will the most severe cases get rapid support for ongoing care costs/loss of earnings etc whilst any legal dispute is ongoing?

The inclusion of a cap of this nature (alongside the other proposed rules and criteria) underlines the need for accessible information and advice/support for patients and their carers/families, to understand the limitations and what this means for them in practice. The more complex the rules and eligibility criteria, the more critical that advice and support for people becomes.

If no, please briefly explain why:
12. The No-fault Review Group recommended that any compensation awarded under the new scheme should be based on need rather than on a tariff based system. We are proposing that the level of compensation for injuries sustained will be based on existing principles including case precedent and the Judicial College Guidelines (formerly the Judicial Studies Board Guidelines). Compensation for patrimonial loss (e.g. past and future wage loss, care and accommodation costs etc.) will require to be assessed on an individual basis often with regard to expert opinion.

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<th>Question 7 - Do you agree that levels of award should be based on the Judicial College Guidelines with patrimonial loss assessed on an individual basis?</th>
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<td>Yes ☒ No ☐</td>
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If you disagree please briefly explain why:

13. As it stands current legislation does not allow Ministers to introduce a redress scheme which makes provision for payment of sums which Health Boards etc. have no legal liability (actual or potential) to pay. A provisional slot has therefore been identified for the introduction of a bill for Primary legislation for a ‘No-Blame Redress Scheme’ in early 2017. The primary legislation and process will be developed, in a manner which would allow the eligibility criteria, cap and scope to be amended at a later date through secondary legislation, if appropriate once the scheme has been established and fully tested.

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<th>Question 8 - Do you agree that the primary legislation should be flexible enough to allow the eligibility criteria and scope of the scheme to be extended at a later date?</th>
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<td>Yes ☒ No ☐</td>
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The scheme will need to be tested, evaluated and changed if necessary. Therefore flexibility is essential.

If you disagree please briefly explain why:

14. The original No-fault Review Group’s recommendations included recommendations that: claimants who fail under the no fault scheme should retain the right to litigate, based on an improved litigation system; claimants who fail in litigation should have a residual right to claim under the no fault scheme; should a claimant be successful under the no fault scheme, any financial award made should be deducted from any award subsequently made as a result of litigation; and that appeal from the adjudication of the no fault scheme should be available to a court of law on a point of law or fact.

15. The proposed No-blame scheme will be compliant with the European Convention of Human Rights and patients will retain the right to go to Court should
they wish. The legislation will, however, protect against ‘double dipping’ i.e. if a patient accepts an award offered under the new No-Blame Scheme they would not then be able to use that to raise a legal claim for negligence. (Please see Item 8 in the consultation document in relation to consideration of an appeal process.)

**Question 9 - Do you agree that the legislation should protect against ‘double dipping’?**

Yes ☒ No ☐

If you disagree please briefly explain why:

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16. The rising costs of continuing care is an area of concern. Some respondents to the previous consultation on the Review Group’s recommendations called for the repeal of S2 (4) of the Law Reform (Personal Injuries) Act 1948[^5], which stipulates that personal injury defendants must disregard NHS care when paying compensation. This means public bodies like the NHS have to fund private care. Repealing this section would allow personal injury defendants to buy NHS and local authority care packages rather than pay for private care.

17. In cases where continuing care is appropriate it is proposed that an independent assessment of the individual care package requirements would be undertaken in each case and a guarantee of treatment and care by the NHS or local authority provided. In circumstances where the package of care or elements of it cannot be provided by the NHS or Local Authority, the relevant NHS Board will be responsible for commissioning these services from alternative providers.

**Question 10 - Would you support the repeal of Section 2(4) of the Law Reform (Personal Injuries) Act 1948 in relation to continuing care costs providing, as proposed, the care package is independently assessed and quality care guaranteed in each case?**

Yes ☒ No ☐

If no please briefly explain why:

In order to maximise existing expertise the No-blame scheme proposed would:

- essentially be a ‘fast track’ element of the existing NHS compensation scheme the Clinical Negligence and Other Risks Scheme (CNORIS). This would be administered by the Central Legal Office with independent medical expert input as appropriate.
- in the main continue to be funded through Boards’ contributions calculated as at present based on claims history and Boards would retain their existing delegated limits. The current scheme excess of £25,000 would also be retained;
- be managed by NHS National Services Scotland, (which currently manages CNORIS).

Question 11 - Would you support the development of a ‘fast track’ element of CNORIS, utilising existing expertise with independent medical expert input?

Yes ☒ No ☐

Several independent experts will be required as whether harm is avoidable or not may be subjective. These should be clinical experts – nursing opinion is required alongside medical input. The independent experts will also be required to provide external quality assurance of the local adverse event review. It is essential the correct ‘expert’ is identified for the case in question and in some cases this may need to be sought outside the Scottish clinical community to ensure true independence.

If no, please briefly explain why:

Question 12 - Do you agree that the creation of an independent appeal panel combined with independent medical input in consideration of the claim and award would provide the appropriate level of independence?

Yes ☒ No ☐

If you disagree please briefly explain why:

The No-blame Scheme will be compliant with the European Convention of Human Rights (ECHR) and allow a right of appeal against the decision of the scheme administrator thereby enjoying an adequate level of independence and impartiality and with sufficient ‘equality of arms’. We will explore the creation of an independent appeal panel and how this would fit into the wider courts and tribunals landscape.
**Question 12.1** – Do you agree that the independent appeal panel will meet the patient’s right to appeal?

[ ] Yes  [ ] No

In order for the right to appeal to be meaningful in practice, it needs to be clarified what independent advice and support will be available to patients and their carers/families to enable them to exercise that right.

If no, please briefly explain why:

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**We are grateful for your response. Thank you.**